K101227

5.0 510(k) Summary or 510(k) Statement

In accordance with 21 CFR 807.87(h) and (21 CFR 807.92) the 510(k) Summary for the Back-Tek device is provided below.

Device Common Name: Infrared Lamp

Device Proprietary Name: Back-Tek

JUN 23 2010

Submitter:
York Biomedical Inc.
8132 Artie Kemp Rd.
Frederick, MD 21701
Phone: 301-788-0702

Contact:
Calley Herzog
Consultant
Biologics Consulting Group, Inc.
Phone: 720-883-3633
Email: cherzog@bcg-usa.com

Classification Regulation: 21 CFR 890.5500

Panel: Physical Medicine

Product Code: ILY

Indication for Use:
The Back-tek system is indicated for the temporary relief of minor muscle and joint pain and stiffness; and the temporary relief of joint pain associated with arthritis, muscle spasms, minor strains and sprains and minor muscular back pain; muscular relaxation; and the temporary increase of local circulation where applied.

Device Description:
The Back-tek device is a far infrared heating device that is provided in a back support belt.

Performance Data:
Skin temperature testing is provided to show that the Back-Tek provides therapeutic heat during the treatment cycle.

Substantial Equivalence:
The Back-Tek device is a far infrared heating device that is substantially equivalent to the Thermotex Platimun Heat Therapy System cleared in K092589 based on indication for use and technological characteristics.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

York Biomedical, Inc.
% Biologics Consulting Group, Inc.
Ms. Calley Herzog
13417 Quivas Street
Westminster, Colorado 80234

JUN 2 3 2010

Re: K101227
Trade/Device Name: Back-Tek
Regulation Number: 21 CFR 890.5500
Regulation Name: Infrared lamp
Regulatory Class: II
Product Code: ILY
Dated: May 3, 2010
Received: May 3, 2010

Dear Ms. Herzog:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4.0 Indications for Use Statement

510(k) Number (if known): _____

Device Name: Back-Tek

Indications For Use:

The Back-tek system is indicated for the temporary relief of minor muscle and joint pain and stiffness; and the temporary relief of joint pain associated with arthritis, muscle spasms, minor strains and sprains and minor muscular back pain; muscular relaxation; and the temporary increase of local circulation where applied.

Prescription Use _____ AND/OR Over-The-Counter Use__X___
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K101227